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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: CHEERIOS MARKETING
AND SALES PRACTICES
LITIGATION**

Case No. 09-2413-PGS-ES

MDL Docket No. 2094

ALL CASES

Hearing Date: July 28, 2010
(Oral Argument Requested)

**DEFENDANT'S MOTION TO DISMISS
PLAINTIFFS' CONSOLIDATED AMENDED COMPLAINT**

Defendant General Mills, Inc. respectfully moves to dismiss the claims against it in the Consolidated Amended Complaint in this action. Defendant also requests that the Court hear oral argument from the parties regarding this Motion.

DATED: April 28, 2010

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**MEMORANDUM OF POINTS AND AUTHORITIES
IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS
PLAINTIFFS' CONSOLIDATED AMENDED COMPLAINT**

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I.
INTRODUCTION AND SUMMARY OF ARGUMENT

Through these private class action lawsuits, Plaintiffs assert that General Mills' truthful and scientifically-proven statements regarding the cholesterol-reducing benefits of Cheerios converted this dried oat breakfast cereal into a "drug." Plaintiffs do not and cannot challenge the broad scientific consensus supporting the link between the soluble fiber found in Cheerios and cholesterol reduction, and their Consolidated Amended Complaint contains *no* allegations of actual deception or injury. Instead, Plaintiffs attempt to base their lawsuits on a nonbinding warning letter from the staff of a district office of the U.S. Food and Drug Administration ("FDA") discussing allegations of possible technical noncompliance with federal drug labeling regulations. These lawsuits followed only days after press reports of that FDA staff letter.

General Mills remains in discussions with the FDA regarding that regulatory inquiry. Since issuing its letter, the FDA has clarified that: (a) General Mills is authorized to claim that consuming Cheerios as part of a healthy diet may lower the risk of coronary heart disease; (b) Americans should consume whole grain products (like Cheerios); and (c) there are no safety concerns with Cheerios.

Plaintiffs' Complaint nevertheless urges this Court to wade into this unresolved FDA regulatory inquiry and substitute a private nationwide class action for the agency's application of its scientific and regulatory expertise. Plaintiffs' lawsuit is not the proper forum for this dispute; the FDA is.

Plaintiffs' state law consumer fraud and warranty claims fail for several independent reasons.

First, each of Plaintiffs' state law theories seeks to impose private damages liability based on alleged technical violations of the FDA regulations described in the FDA staff letter. But federal law expressly preempts Plaintiffs' attempt to impose new labeling requirements, and there is no private right of action to enforce alleged violations of FDA regulations even if Plaintiffs were able to show that General Mills is out of compliance with them (which it is not).

Second, the primary jurisdiction doctrine requires dismissal because: (a) the core question of regulatory compliance involves technical and policy questions within the FDA's expertise; (b) adjudicating these issues through private litigation risks inconsistent regulatory determinations; and (c) there is an ongoing dialogue with the FDA.

Third, Plaintiffs' claims fail for several independent reasons based on *state* law:

- Counts I-IV fail because Plaintiffs are residents of California, New York, and New Jersey, they made their purchases in those states, and there is no basis for applying Minnesota law (or the laws of any other state where Plaintiffs do not reside);
- Plaintiffs have not alleged violations of state consumer protection laws (Count V) because they do not and cannot claim that the Cheerios labels were actually or potentially deceptive. Plaintiffs also do not claim that they suffered physical harm from consuming Cheerios, or that General Mills failed to deliver what was promised—a dried oat cereal containing soluble fiber that may lower “bad” cholesterol when consumed daily as part of a healthy diet. Courts

have consistently rejected similar attempts to equate *alleged regulatory noncompliance* with *actual or potential deception*;

- The state law warranty claims (Counts VI-VII) fail because Plaintiffs do not and cannot allege the terms of any specific (or implied) warranty that General Mills allegedly breached; and
- Plaintiffs cannot assert an equitable theory of unjust enrichment (Count VIII) because this is not a valid cause of action under California law, their allegation that a binding contract governs the parties' rights precludes this quasi-contractual remedy as a matter of law, and they do not allege any facts that would entitle them to this relief.

General Mills respectfully requests that the Court dismiss the Complaint.

II.

SUMMARY OF ALLEGED FACTS

A. The Parties. The Consolidated Amended Complaint alleges that Plaintiffs, who are residents of California, New Jersey, and New York, purchased Cheerios in those states during an unspecified "class period." (Consol. Am. Compl. [Docket No. 21] ("Compl.") ¶¶ 5-10.) Defendant General Mills is a leading producer of food products that markets some of the world's most recognized and best-loved brands, including Betty Crocker, Pillsbury, Green Giant, and Yoplait. General Mills has manufactured and sold Cheerios since 1941.

B. The Cheerios Labeling At Issue. In 2003, the FDA announced its "Consumer Health Information for Better Nutrition Initiative," which reflected the agency's "twin goals of making available better, easily understood, up-to-date scientific information about how dietary choices can affect health, as well as encouraging companies to compete based on health and nutrition

consequences” (Ex. A [citing FDA Press Release, “FDA to Encourage Science-based Labeling and Competition for Healthier Dietary Choices,” July 10, 2003].) General Mills supported this initiative by investing millions of dollars in clinical studies of its products and by conveying nutritional information (supported by scientific evidence and government dietary guidelines) to help consumers make healthy and informed dietary choices.

The Cheerios labels contained scientifically-supported, non-misleading statements about the health effects of the cereal. Some labels reported the results of a clinical trial of Cheerios, which was consistent with other published, peer-reviewed studies,¹ that showed a 4% reduction in LDL (“bad”) cholesterol after 6 weeks of consuming 3 grams of soluble fiber from Cheerios daily:

Did you know that in just 6 weeks Cheerios can reduce bad cholesterol by an average of 4 percent? Cheerios is ... clinically proven to lower cholesterol. A clinical study showed that eating two 1½ cup servings daily of Cheerios cereal reduced bad cholesterol when eaten as part of a diet low in saturated fat and cholesterol.

(Compl. ¶ 33.) These and similar statements constituted the “4-in-6” claim.

Other labels reported the results of another published clinical trial that demonstrated a 10.7% reduction in bad cholesterol in one month as a result of a

¹ Ex. B [L. Johnston, et al., *Cholesterol-Lowering Benefits of a Whole Grain Oat Ready-To-Eat Cereal*, 1 Nutrition in Clinical Care 6 (1998)]; see also Ex. C [H. Reynolds, et al., *Whole Grain Oat Cereal Lowers Serum Lipids*, 15 Topics in Clinical Nutrition 74 (2000)]; Ex. D [W. Karmally, et al., *Cholesterol-Lowering Benefits of Oat-Containing Cereal in Hispanic Americans*, 105 J. Am. Diet Ass’n 967 (2005)].

reduced calorie, low-fat diet including Cheerios.² This was the “10-in-1” claim.

These studies echo the surrounding body of scientific literature examining the cholesterol-reducing effects of soluble fiber. Federal regulations specifically acknowledge this science. *See, e.g.*, 21 C.F.R. § 101.77(b)(4) (“Results of numerous studies have shown that fiber-containing ... grain products can help lower [bad] cholesterol.”). The FDA also cited and relied on research showing that people who consumed “whole grain oat cereal experienced a significant decrease in total cholesterol (4.4 percent or 10.0 milligrams (mg)/deciliter (dL)) and LDL-cholesterol (4.9 percent or 7.8 mg/dL).” 62 Fed. Reg. 3584, 3586 (Jan. 23, 1997). Based on this research, the agency adopted regulations authorizing food labels that explain the link between soluble fiber from whole oats and a reduction in the risk of coronary heart disease through cholesterol reduction. 21 C.F.R. § 101.81(d)(2)-(3). General Mills complies with these regulations by explaining the benefits of consuming Cheerios as part of a healthy diet. (*Infra* pp. 10-12.)

C. The FDA’s Regulatory Inquiry And Plaintiffs’ Lawsuit. The Complaint relies almost exclusively on a nonbinding letter from the FDA’s Minneapolis District Office on May 5, 2009. (Compl., Ex. 1.) According to that letter, because Cheerios is not “generally recognized as safe and effective in preventing or treating

² Ex. E [K. Maki, et al., *Whole-Grain Ready-to-Eat Oat Cereal, as Part of a Dietary Program for Weight Loss, Reduces Low-Density Lipoprotein Cholesterol in Adults with Overweight and Obesity More than a Dietary Program Including Low-Fiber Control Foods*, 110 J. Am. Diet. Ass’n 205 (2010)].

hypercholesterolemia or coronary heart disease,” General Mills should have submitted a “new drug” application for the dried oat cereal. (*Id.* at 2.)

The FDA has not at any point challenged the truth of Cheerios’ labeling. This is understandable, because General Mills based its claims on peer-reviewed research results that are consistent with the FDA’s own findings. The staff letter instead focused on the technical, regulatory question of whether General Mills should be prohibited from making a specific percentage reduction claim (the “4-in-6” claim), even though it is true.

In particular, the FDA staff letter applied 21 C.F.R. § 101.81—which addresses the relationship between soluble fiber from whole grain oats and coronary heart disease—to the “4-in-6” claim. (Compl. ¶ 33; Ex. 1, at 1-2.) The staff argued that this claim did not satisfy Section 101.81 because (1) although the “4-in-6” claim instructed consumers to consult the back of the Cheerios box (“SEE BACK FOR DETAILS”) where the study substantiating the claim was cited, the font size, format, and design allegedly did not meet FDA standards, and (2) the claim improperly attributed a specific degree of risk reduction to “diets that include” Cheerios. (*Id.* at 2.) The staff also stated that this alleged noncompliance supported classifying Cheerios as a “drug” that could not be marketed without FDA approval. (*Id.* at 1-2.)

Next, the FDA staff letter focused on two statements made on General Mills’

“Whole Grain Nation” website,³ which the staff erroneously deemed to be part of the Cheerios labeling because the cereal boxes referred to the website address. (*Id.* at 2-4.) The staff argued that website statements concerning “the risk of heart disease” and “the risk of some cancers” departed from the approved wording in 21 C.F.R. § 101.77 and § 101.76, respectively. (*Id.* at 3-4.)

The FDA staff asserted that “[f]ailure to promptly correct the violations ... *may* result in enforcement action without further notice,” but the letter did not recommend any specific remedy. (*Id.* at 4 (emphasis added).) No enforcement action has been initiated.

Only nine days after the initial staff letter, the FDA clarified that General Mills was authorized “to claim that [Cheerios] may lower the risk of coronary heart disease when eaten as part of a diet low in saturated fat and cholesterol,” in light of the “significant scientific agreement among qualified experts to support the relationship between soluble fiber in whole oats and coronary heart disease.”

(Ex. F [FDA Questions And Answers (May 14, 2009), *available at*

<http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm161795.htm>].) The

FDA also stressed that federal dietary guidelines encourage Americans to consume

³ This site stated that “[h]eart-healthy diets rich in whole grain foods can reduce the risk of heart disease” and that “[i]ncluding whole grain as part of a healthy diet may ... [h]elp reduce the risk of certain types of cancers. Regular consumption of whole grains as part of a low-fat diet reduces the risk for some cancers, especially cancers of the stomach and colon.” (Compl., Ex. 1, at 2.)

whole grain foods such as Cheerios, and that there are no safety concerns with the cereal. (*Id.*) The FDA staff later agreed that the Johnston study “provide[s] data that soluble fiber from whole oats can lower LDL cholesterol by an average of 4% in six weeks.” (Ex. G, at 2.) General Mills and the FDA remain in discussions over these labels (Exs. A, G-I), and the FDA has not provided a final position on the Cheerios labeling (Ex. G).

General Mills revised the Cheerios packaging at issue in May 2009 and is no longer using the “4-in-6” or “10-in-1” claims on Cheerios labels, in its print or television advertising, or on the websites cited in the Complaint. (Decl. of Jeff Hingher ¶¶ 4-7.)⁴

Plaintiffs’ Complaint does not challenge the broad scientific consensus supporting the health benefits of soluble fiber in whole oats, nor does it allege that Cheerios is not healthy. Instead, Plaintiffs suggest that the Cheerios labeling was “deceptive” because the cereal was “improperly portray[ed]” as “having properties that reduce cholesterol, the risk of heart disease and the risk of certain cancers, *irrespective of other important dietary considerations.*” (Compl. ¶ 46 (emphasis added).) The sole basis for Plaintiffs’ attack on the Cheerios labeling is the FDA

⁴ The only current Cheerios labeling claim cited in the Complaint is the soluble fiber/heart disease claim, which the FDA acknowledged is “authorized” (Compl., Ex. 1, at 2), and the related statement that Cheerios “helps lower cholesterol,” which was not challenged in the FDA staff letter. (*Id.* [“[T]he lower left corner of the Cheerios front label contains a soluble fiber/coronary heart disease health claim authorized under 21 C.F.R. § 101.81”]; Compl. ¶ 36.)

staff letter (*id.* ¶¶ 33-44), which the agency itself characterizes as “informal and advisory.” (Ex. J [FDA, *Regulatory Procedures Manual* § 4-1-1 at 4-2 (Mar. 2009 ed.), available at <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProcedures.Manual/UCM074330.pdf>].)

Plaintiffs’ Complaint asserts eight counts on behalf of a nationwide class of consumers: alleged violations of (1) the Minnesota Prevention of Consumer Fraud Act, Minn. Stat. § 325F.68, (2) the Minnesota Unlawful Trade Practices Act, *id.* § 325D.09, (3) the Minnesota Deceptive Trade Practices Act, *id.* § 325D.44, (4) the Minnesota False Statement in Advertising Act, *id.* § 325F.67, and (5) the consumer protection statutes of 39 states and the District of Columbia; (6) breach of express warranty in violation of the laws of 36 states (and D.C.); (7) breach of implied warranty under the laws of 30 states (and D.C.); and (8) unjust enrichment. (Compl. ¶¶ 61-138.) Plaintiffs seek actual, statutory, and punitive damages; declaratory and injunctive relief; and attorneys’ fees. (*Id.* pp. 34-35.)

III. THE LEGAL STANDARD GOVERNING THIS MOTION

Rule 12(b)(6) requires dismissal if the complaint does not contain “enough facts to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice” to meet the pleading standard. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). *See also id.* (“A pleading that offers ‘labels and conclusions’ or ‘a formulaic recitation of

the elements of a cause of action will not do.”) (quoting *Twombly*, 550 U.S. at 555); *Glenz v. RCI, LLC*, No. 09-378, 2010 WL 323327, at *2 (D.N.J. Jan. 20, 2010) (rejecting “bald assertions, unsupported conclusions, unwarranted inferences, or sweeping legal conclusions cast in the form of factual allegations”).

IV.

PLAINTIFFS MAY NOT BASE THIS ACTION ON ALLEGED VIOLATIONS OF THE FDCA OR FDA REGULATIONS

Dismissal is appropriate here because federal law preempts Plaintiffs’ claims, General Mills’ labeling complies with the Federal Food, Drug and Cosmetic Act (“FDCA”) and FDA regulations, and Plaintiffs cannot assert alleged violations of those laws through this private action.

A. Federal Law Expressly Preempts Plaintiffs’ Claims

The FDCA expressly preempts Plaintiffs’ attempt to use their state court claims to impose new and different labeling requirements beyond those contained in federal law. *See* 21 U.S.C. § 343-1(a)(3) (preempting any state “requirement for the labeling of food” that is “not identical to” federal requirements).

The federal regulatory scheme generally prohibits health claims “unless” they are authorized by FDA regulations (or subject to another exception not at issue here). *Id.* §§ 343(r)(1)(B) & (r)(3)(B)(i). Section 343(r) also regulates labeling that “characterizes the relationship of any nutrient ... to a disease or a health-related condition.” *Id.* The regulations implementing Section 343(r) provide that General Mills “may state” that the heart-healthy benefits of soluble fiber result from the intermediate link of lowering “blood cholesterol” if the claim:

- (1) uses specific, authorized terms (like “coronary heart disease,” “soluble fiber” (and identifies its source), “saturated fat,” and “cholesterol” (when referring to fat));
- (2) does not provide any specific degree of risk reduction in heart disease or imply that the specified diet is the only means to reduce that risk;
- (3) explains that diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods “may” or “might” reduce the risk of heart disease; and
- (4) specifies the daily dietary intake of the soluble fiber source that is necessary (3g or more per day).

21 C.F.R. § 101.81. Section 101.81 authorizes *any* health claim that complies with these criteria.

General Mills complied with these requirements because the Cheerios labels (1) contained all the specified terms and language; (2) did not promise any reduction in the risk of heart disease (as opposed to a potential reduction in *bad cholesterol*); (3) explained that consuming soluble fiber (as part of a healthy diet) “*may*” reduce bad cholesterol (and the FDA later clarified that General Mills was authorized to “claim that [Cheerios] may lower the risk of coronary heart disease when eaten as part of a diet low in saturated fat and cholesterol”); and (4) identified the necessary serving sizes and daily dietary intake. (Compl. ¶¶ 21-24; *see also* Ex. A at 4-5.) Because the regulations authorize the Cheerios labeling, by definition the health claims also comply with Section 343(r). *See* 21 U.S.C. §§ 343(r)(1)(B) & (r)(3)(B)(i) (prohibiting health claims “unless” authorized by “regulations” issued by the FDA).⁵ General Mills’ compliance bars this action as a

⁵ In addition, the statements on General Mills’ websites are permissible dietary

[Footnote continued on next page]

matter of law. *See id.* § 343-1(a)(5).

The nonbinding FDA staff letter does not change this analysis. The FDA staff letter, and Plaintiffs' claim based on that letter, suggest that Cheerios advertising was improper for reasons that are *not* listed in Section 101.81. First, the nonbinding FDA staff letter states that the cholesterol-lowering information appeared more prominently than other information on the Cheerios label. (Compl., Ex. 1, at 2.) But Section 101.81 imposes no restrictions related to the placement of information on food labels. Second, the FDA staff erroneously asserted that General Mills could not claim a specific degree of reduction in cholesterol. (*Id.*) Once again, however, the regulation does not support that position. While Section 101.81 does not allow a claim that attributes to a food any reduction in risk for coronary heart disease, it does not prohibit statements describing a degree of reduction in cholesterol levels.⁶

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guidance statements and not unauthorized health claims. 68 Fed. Reg. 66040, 66046 (Nov. 25, 2003) (“[A] claim about the benefits of a broad class of foods (*e.g.*, fruits or vegetables)” that does not make a “connection to a substance found in that class of foods” is a form of dietary guidance and not a health claim). The FDA’s example dietary guidance statement is nearly identical to the statements on General Mills’ websites. (*Compare id.* [“Diets rich in fruits and vegetables may reduce the risk of some types of cancer and other chronic diseases.”] *with* Compl. ¶ 30 [Whole Grain Nation website: “Including whole grain as part of a healthy diet may ... [h]elp reduce the risk of certain types of cancers.”].)

⁶ The FDA also presumes that its authority extends to the Whole Grain Nation website simply because the Cheerios labels referenced this website address. (*Id.*) The FDA did not (and cannot) provide any specific authority for this position.

Obviously, any failure to comply with “requirements” that appear nowhere in Section 101.81 cannot amount to a violation of Section 101.81. But that is what Plaintiffs allege. The FDCA expressly preempts “any [state] requirement” respecting “any” such health claims that is “*not identical*” to Section 343(r) and federal regulations. *Id.* § 343-1(a)(5) (emphasis added). *See also* 21 C.F.R. § 100.1(c)(4) (state laws cannot “directly or indirectly impose[] obligations” concerning the composition or labeling of food that either (1) are “not imposed by or contained in,” or (2) “differ from,” the applicable provision “including any implementing regulation” of the FDCA). Because Plaintiffs seek to impose additional restrictions beyond those “contained in” federal law, Section 343-1 expressly preempts this lawsuit.

In similar circumstances, the Supreme Court held that federal law preempted a California labeling requirement related to “moisture loss” variations that was not identical to regulations implementing the Federal Meat Inspection Act, which has a preemption provision virtually identical to Section 343-1. *Jones v. Rath Packing Co.*, 430 U.S. 519, 530-32 (1977). *See also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (holding that the FDCA’s medical device preemption provision in Section 360k(a)(1), which is materially identical to Section 343-1(a)(5), preempted state common law claims); *Nat’l Broiler Council v. Voss*, 44 F.3d 740, 745-47 (9th Cir. 1994) (Poultry Products Inspection Act, which contains materially identical preemption language, preempted California regulation that was “not identical” to federal regulations); *Mills v. Giant of Md., LLC*, 441 F. Supp. 2d 104, 106-09

(D.D.C. 2006) (rejecting plaintiffs’ attempt to litigate new milk labels that imposed additional requirements beyond federal regulations issued pursuant to Section 343-1(a) of the FDCA); *Shepard v. DineEquity, Inc.*, No. 08-2416, 2009 U.S. Dist. LEXIS 97245, at *15 (D. Kan. Sept. 25, 2009) (holding that Section 343(r) of the FDCA preempted state law claims based on allegedly deceptive nutritional information on restaurant menus). Likewise, the FDCA expressly preempts Plaintiffs’ attempt to litigate new restrictions here.

B. Even If There Were Some Technical Noncompliance With FDA Regulations, Plaintiffs May Not Use This Private Action To Enforce Alleged Regulatory Violations

But even if Plaintiffs could show that the challenged statements did not comply with federal law, their Complaint still fails because there is no private right of action to assert the regulatory violations that are at the heart of this action. The Complaint recites the FDA staff letter at length, and each claim rests upon Plaintiffs’ assertion that the Cheerios labeling violated the FDCA and FDA regulations. (Compl. ¶¶ 33-44, 61, 69, 77, 85, 93, 101, 108, 120, 133.)

“Like substantive federal law itself, private rights of action to enforce federal law must be created by Congress.” *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001). Here, Congress not only created no private rights of action to enforce federal food labeling laws, it gave *exclusive* enforcement authority to the Executive Branch: “[A]ll such proceedings for the enforcement, or to restrain violations, of this Act ... *shall* be by and in the name of the United States.” 21 U.S.C. § 337(a) (emphasis added); *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349 n.5

(2001) (“[T]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance.”).

In addition, both the FDA and federal courts have recognized that communications such as the staff letter are *not* judicially-reviewable “final agency action[s]” and “do[] not commit FDA to taking enforcement action.” (Ex. J at 4-2.) Instead, these letters are simply “informal and advisory” communications from subordinate FDA employees. (*Id.*)⁷

Plaintiffs’ lawsuit seeks to bypass these statutory limitations and convert a warning letter that does not represent a final agency determination into a vehicle for private monetary relief (including punitive damages). As in *Buckman*, Plaintiffs are not “relying on traditional state tort law which had predated the federal enactments in question[],” but instead “the existence of these federal enactments is a critical element in their case.” 531 U.S. at 353. Because their “misrepresentation” claims are “nothing more than a proxy” for alleged regulatory violations, the Court should dismiss the Complaint with prejudice. *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, No. MDL 08-1934, 2009 WL

⁷ See also *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1378 (9th Cir. 1983) (“[S]uch letters do not commit the FDA to enforcement action. Moreover, the availability of relief within the agency [in particular, by citizen petition] refutes the argument that the agency determination is final.”); *Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 586 F.3d 500, 508 (7th Cir. 2009) (“We can set aside the letters from subordinate officials of the FDA; the letters are not final agency action binding on the district court.”).

1703285, at *5 (C.D. Cal. Jun. 17, 2009) (dismissing amended complaint on the ground that “it constitutes yet another attempt to shoehorn allegations that Amgen engaged in off-label promotion in violation of the FDCA into ... state consumer fraud causes of action”). *See also PhotoMedex Inc. v. Irwin*, No. 07-56672, 2010 U.S. App. LEXIS 7640, at *9 (9th Cir. Apr. 14, 2010) (“Because the FDCA forbids private rights of action under that statute, a private action brought under the Lanham Act may not be pursued when, as here, the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation.”); *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993) (dismissing a similar attempt to evade the FDCA’s bar on private enforcement “by ingenious pleading”).

To the extent Plaintiffs have any serious desire for change in the product labeling, or a colorable grievance (and they do not), their authorized recourse is to submit a complaint to the FDA and/or petition for new regulations or administrative action regarding the Cheerios labels. *See* 21 C.F.R. § 10.30.⁸

⁸ Plaintiffs’ reliance on the California Sherman Food, Drug, and Cosmetic Law (Compl. ¶ 101) cannot overcome the federal bar on private enforcement. Although *Farm Raised Salmon Cases*, 175 P.3d 1170, 1173 (Cal. 2008), determined that a complaint was “independent” of the FDCA because it invoked the Sherman Law and because the defendant allegedly violated parallel and identical state and federal disclosure laws, that court did not identify any basis for inferring a federal private damages remedy based on violations of either the FDCA or state statutes that merely incorporate the FDCA by reference. In any event, such an erroneous interpretation of a federal statute does not bind federal courts, and there is good reason not to follow it here. *See, e.g., Fraker v. KFC Corp.*, No. 06-1284, 2007

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V.

**THE PRIMARY JURISDICTION DOCTRINE MANDATES DISMISSAL
OF PLAINTIFFS' ACTION TO ALLOW THE FDA AN OPPORTUNITY
TO INTERPRET ITS OWN REGULATIONS**

If there is any doubt about whether the Cheerios labels were permitted by the FDCA, the Court should “dismiss[] the suit on the ground that the [FDA] has primary jurisdiction.” *Allnet Commc’n Serv., Inc. v. Nat’l Exch. Carrier Ass’n, Inc.*, 965 F.2d 1118, 1120 (D.C. Cir. 1992). This doctrine “requires judicial abstention in cases where protection of the integrity of a regulatory scheme dictates preliminary resort to the agency which administers the scheme.” *United States v. Phila. Nat’l Bank*, 374 U.S. 321, 354 (1963).

Each of the factors that courts in this district have used to determine whether to apply the primary jurisdiction doctrine supports dismissal here. *See generally Clark v. Actavis Group hf*, 567 F. Supp. 2d 711, 715 (D.N.J. 2008).

First, the “question at issue is particularly within the agency’s discretion.” *Id.* Congress entrusted the key interpretative and policy questions at issue here to the Executive Branch. *See* 21 C.F.R. § 10.25(b) (“FDA has *primary jurisdiction* to make the initial determination on issues within its statutory mandate.”) (emphasis added); 21 U.S.C. §§ 371(a), 393(b)(2)(A) & (d)(2). This case “requires resolution

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WL 1296571, at *4 (S.D. Cal. Apr. 30, 2007) (“To overlay the state law tort system over the FDCA would significantly increase the burdens on the FDA to ensure uniform enforcement of its administrative duties.”).

of issues” within the FDA’s “special competence.” *Delta Traffic Serv., Inc. v. Occidental Chem. Corp.*, 846 F.2d 911, 912 n.3 (3d Cir. 1988) (citation omitted).

Second, the core question of FDCA compliance “involves technical or policy considerations within the agency’s particular field of expertise.” *Clark*, 567 F. Supp. 2d at 715. Dismissal is particularly appropriate here so that the FDA may apply its expertise to the meaning of its own regulations. *See, e.g., In re Human Tissue Prods. Liab. Litig.*, 488 F. Supp. 2d 430, 432 (D.N.J. 2007) (“Under the doctrine of ‘primary jurisdiction,’ when an activity is arguably subject to an administrative agency’s expertise, such as the FDA, federal courts must defer to the exclusive competence of that agency.”). General Mills complies with existing FDA regulations and its labeling reports truthful scientific information, but any dispute over technical compliance belongs in the FDA’s arena.

Other courts have dismissed similar consumer fraud claims where the FDA was “better suited to address the scientific issue[s]” involved in food labeling. *Physicians Comm. for Responsible Medicine v. General Mills, Inc.*, No. 05-958, 2006 WL 3487651, at *6 (E.D. Va. Nov. 30, 2006) (“*PCRM*”), *aff’d*, 283 Fed. Appx. 139 (4th Cir. 2008) (dismissing state law complaint under the primary jurisdiction doctrine because “the FDA is better suited to address the scientific issue of the effects of dairy product consumption on weight gain and fat

burning.”).⁹ As in these cases, dismissal here is both “sensible and proper because courts are not expert on the medical and scientific issues which must be explored in order to produce accurate labeling.” *United States v. An Article of Device ... Diapulse*, 650 F.2d 908, 910 (7th Cir. 1981) (citation omitted).

Third, this case raises “a substantial danger of inconsistent rulings.” *Clark*, 567 F. Supp. 2d at 715. Adjudicating this action before the responsible agency acts would invite varied interpretations of FDA labeling regulations—the very harm that the primary jurisdiction doctrine seeks to avoid. *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 64 (1956) (primary jurisdiction doctrine ensures “uniformity”); *PCRM*, 2006 WL 3487651, at *6 (explaining that “there is clearly a risk of inconsistent judgments if all three proceedings were allowed to proceed independently”).

Fourth, another factor that courts have considered is whether “a prior application to the agency has been made.” *Clark*, 567 F. Supp. 2d at 715. As in *Clark*, Plaintiffs “have not made a prior application to the FDA,” but “this failure

⁹ See also *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230-31 (3d Cir. 1990) (holding that the FDA had primary jurisdiction to decide whether certain inert sugary liquids were properly labeled “active” or “inactive” ingredients, a question that the agency had not conclusively answered); *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008) (applying primary jurisdiction doctrine because plaintiff’s claim “implicate[d] technical and policy questions that should be addressed in the first instance by the agency with regulatory authority over the relevant industry rather than by the judicial branch”).

is not dispositive.” *Id.* at 719; *In re Human Tissue Prods.*, 488 F. Supp. 2d at 433 (same). As Plaintiffs’ reliance on the FDA staff letter establishes, the agency is already examining the same questions regarding the labeling of Cheerios.¹⁰

If Plaintiffs are unsatisfied with the pace of the FDA’s inquiry, then their recourse is to petition the agency, not institute a private lawsuit. *Clark*, 567 F. Supp. 2d at 718-19 (rejecting the argument that “undue delay” would result were plaintiffs to “seek[] redress in the form of a Citizen’s Petition, pursuant to 21 C.F.R. § 10.30”). Once an issue has been committed to FDA expertise, the primary jurisdiction doctrine bars parallel proceedings in federal court. The Court should dismiss or stay this action until the FDA reaches a final determination on the regulatory issues that lie squarely within its mandate.

VI. **EACH OF PLAINTIFFS’ CLAIMS FAILS AS A MATTER OF LAW**

Plaintiffs’ state law causes of action fail for several reasons: (1) Plaintiffs are not Minnesota residents and cannot invoke that state’s law; (2) they cannot establish a violation of other state consumer protection laws; (3) Plaintiffs do not allege facts to show a breach of any warranty; and (4) they cannot obtain injunctive relief because the challenged statements no longer appear on the Cheerios labels.

¹⁰ Moreover, while these Plaintiffs have not petitioned the FDA, the plaintiff in the case now pending in D.C. Superior Court expressly alleges that it is responsible for prompting the FDA’s review of Cheerios labeling, and this plaintiff has attached to its complaint in that case its letter petitioning the FDA to take enforcement action. (*See* Ex. K [NCL Compl. ¶ 3].)

A. Plaintiffs Lack Any Cognizable Connection To Minnesota And They Cannot Assert Claims Under That State’s Law Or Any Other State Where They Have No Relevant Contacts

Not one plaintiff here is from Minnesota, and yet Counts I through IV purport to allege violations of Minnesota statutes. Plaintiffs cannot invoke Minnesota law instead of the laws of the states where they reside and allegedly purchased Cheerios—California, New Jersey, and New York. This is prohibited both by applicable choice-of-law rules and well-settled constitutional doctrines.

Choice-of-law principles bar Plaintiffs’ attempt to apply Minnesota law in this case. In federal multidistrict forums like this one, the court applies “the choice of law rules of the transferor courts,” *Ford Motor Co. Ignition Switch Prods. Liab. Litig.*, 174 F.R.D. 332, 348 (D.N.J. 1997)—here, California, New Jersey, and New York. The Third Circuit and courts in this District have held that in multi-state consumer protection class actions alleging deception and misrepresentation claims, New Jersey choice-of-law rules dictate that “each prospective plaintiff’s home state has the most significant interest in litigating its residents’ claims.” *Agostino v. Quest Diagnostics Inc.*, 256 F.R.D. 437, 463 (D.N.J. 2009); *see also Cooper v. Samsung Elecs. Am., Inc.*, No. 08-4736, 2010 WL 1220946, at *4 (3d Cir. Mar. 30, 2010); *Nafar v. Hollywood Tanning Sys., Inc.* 339 Fed. Appx. 216, 220-21 (3d Cir. 2009). California and New York choice of law rules compel the same result. *See, e.g., In re Grand Theft Auto Video Game Consumer Litig.*, 251 F.R.D. 139, 149-50 (S.D.N.Y. 2008) (applying California and New York consumer fraud, warranty, and unjust enrichment laws to claims in MDL class action by plaintiffs who made

their purchases in those states).¹¹

Here, the only applicable laws are those of each Plaintiff's home state. Plaintiffs argued that California, New Jersey, and New York law applied to their claims when they filed their individual complaints.¹² Pretrial consolidation through the MDL process does not alter the analysis, and Plaintiffs still allege contacts with only the states where they reside and allegedly purchased Cheerios. (Compl. ¶¶ 5-10.) The laws of those three states must govern this action and guide the Court's ruling on this Motion.

Minnesota law does not apply here simply because General Mills is headquartered there or because Plaintiffs allege that all key decisions were made there. In fact, Third Circuit precedent expressly rejects this argument. *See*

¹¹ *In re Mercedes-Benz Tele Aid Contract Litig.*, No. 07-2720, 2010 WL 931865, at *28 (D.N.J. Mar. 15, 2010), reached a different conclusion than *Agostino* by (among other errors) treating the Third Circuit's decision in *Nafar* as "limited to the facts of that case, and one that has no bearing on the present litigation." *Id.* But that approach violates the traditional treatment of unpublished court of appeals decisions as "considerable persuasive authority," *Marracco v. Kuder*, No. 08-713, 2009 WL 235469, at *2 (D.N.J. Jan. 30, 2009), and "highly persuasive" authority when directly on point. *Construcciones Haus Soceidad v. Kennedy Funding Inc.*, No. 07-0392, 2008 WL 1882857, at *4 n.3 (D.N.J. Apr. 24, 2008) (Sheridan, J.). *Mercedes* also cannot be reconciled with the Third Circuit's decision in *Cooper*, which also rejected application of New Jersey law by a nonresident named plaintiff. 2010 WL 1220946, at *4.

¹² *See, e.g., Huey* Compl. ¶¶ 3, 36-83 (E.D. Cal.) [California plaintiff asserting claims under California law]; *Myers* Compl. ¶¶ 5, 34-61 (D.N.J.) [New Jersey plaintiff asserting claims under New Jersey law]; *Stevens* Compl. ¶¶ 16, 69-104 (E.D.N.Y.) [New York plaintiff asserting claims under New York law].

Cooper, 2010 WL 1220946, at *4 (rejecting contention that New Jersey consumer protection law applied because defendant was headquartered in New Jersey, the alleged misrepresentations were conceived of and created in New Jersey, and the fraud was orchestrated from New Jersey); *Agostino*, 256 F.R.D. at 460-65 (same); *In re Ford Motor Co.*, 174 F.R.D. at 347-48 (same). *See also In re Bridgestone/Firestone, Inc.*, 288 F.3d 1012, 1016 (7th Cir. 2002) (“Neither Indiana nor any other state has applied a uniform place-of-the-defendant’s-headquarters rule to products-liability cases.”).¹³

And adoption of any such rule would plainly violate constitutional limits on the extraterritorial reach of a single state’s law to regulate the rights and responsibilities of parties in all 50 states. This will be particularly important at the class certification stage, because the Supreme Court has squarely held that, as a matter of Due Process, a court cannot apply the laws of a single state to a nationwide class where the laws applicable to class members in other states conflict. *See Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 817-18 (1985). And these laws do conflict. *See, e.g., In re St. Jude Medical, Inc.*, 425 F.3d 1116, 1120

¹³ Likewise, Plaintiffs’ assertion that Minnesota law applies to a controversy over consumer access to the General Mills website (Compl. ¶ 12) does not support the nationwide application of Minnesota law because there is no allegation that any of the named Plaintiffs ever visited that website. (*Infra* n. 18.) Further, even if Plaintiffs visited that site, the law of their domicile states—not Minnesota—would apply. *See, e.g., Clark v. Info. Solutions, Inc.*, No. 03-7882, 2005 U.S. Dist. LEXIS 8243, at *8-11 (N.D. Ill. Apr. 26, 2005).

(8th Cir. 2005) (““State consumer-protection laws vary considerably, and courts must respect these differences rather than apply one state’s law to sales in other states with different rules.””) (quoting *In re Bridgestone/Firestone, Inc.*, 288 F.3d at 1018).

Like the Due Process Clause, the Full Faith and Credit and Commerce Clauses likewise require respect for the various laws of the states where Plaintiffs reside and allegedly suffered injury, and, together with the Due Process Clause, they create a presumption that states cannot apply their laws to transactions that occur outside their borders. *Phillips Petroleum*, 472 U.S. at 817-19, 821-22; *see also State Farm Mutual Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 421-22 (2003). Thus, federal courts have repeatedly rejected the “novel[]” assumption that “one state’s [consumer protection] law would apply to claims by consumers throughout the country.” *Bridgestone/Firestone*, 288 F.3d at 1016. Indeed, the Eighth Circuit has reversed a certified nationwide class under Minnesota law and held that Minnesota law cannot be applied nationwide at the expense of out-of-state consumers’ “federal constitutional [due process] rights.” *In re St. Jude Medical*, 425 F.3d at 1120.

Because it is evident from the pleadings that Minnesota law does not apply to any of Plaintiffs’ claims, the Court should dismiss Counts I-IV along with the Minnesota claims alleged in Counts V-VIII. (Compl. ¶¶ 116(n), 129(m), 134.) In a putative class action, claims pleaded under an *inapplicable* state law do not survive a motion to dismiss. *See Cooper*, 2010 WL 1220946, at *4.

For similar reasons, the Court should dismiss Counts V, VI and VII, which purport to assert claims under the allegedly “similar” consumer fraud and warranty laws of 45 other states (and the District of Columbia). (Compl. ¶¶ 94, 97, 109, 116, 121, 129.) As a preliminary matter, Plaintiffs failed to satisfy the notice requirements of several state consumer protection laws invoked in Count V. Plaintiffs tried to provide “notice” on the *same day* they filed their Consolidated Amended Complaint, but this is insufficient.¹⁴ Plaintiffs also do not even bother to allege *any* connection with the dozens of other states listed in Counts V-VII. Courts in this District have dismissed similar “catch-all” state law counts on this basis. *See, e.g., Kalow & Springnut, LLP v. Commence Corp.*, No. 07-3442, 2009 WL 44748, at *5 (D.N.J. Jan. 6, 2009); *In re Toshiba Am. HD DVD Mktg. & Sales Prac. Litig.*, No. 08-939, 2009 WL 2940081, at *14 (D.N.J. Sept. 11, 2009).

Plaintiffs cannot preserve these “kitchen-sink” counts by asserting claims on behalf of a putative class. Unless and until certification, Plaintiffs may only bring claims on their own behalf. *Hale*, 2009 WL 321579, at *6 (citing *Rolo v. City Inv. Co. Liquidating Trust*, 155 F.3d 644, 659 (3d Cir. 1998)).

¹⁴ *See* Conn. Gen. Stat. § 42-110g(c) (requiring notice to state officials); 815 Ill. Comp. Stat. Ann. § 505/10a(d) (same); La Rev. Stat. § 51:1409.B (same); Ga. Code Ann. § 10-1-399(b) (requiring 30 days’ notice to defendant); Me. Rev. Stat. Ann. tit. 5 § 213.1-A (same); Mass. Gen. Laws Ann. ch. 93A, § 9(3) (same).

B. Plaintiffs' Allegations Fall Far Short Of Alleging Facts To Show Violations Of The Consumer Protection Statutes

1. Plaintiffs Have Alleged No Deceptive Conduct

Plaintiffs do not and cannot allege facts to establish that General Mills' conduct—reporting scientifically-supported health information on Cheerios labeling—violated any state consumer protection and false advertising laws, including the California, New Jersey, and New York laws that require deceptive or misleading conduct. *See In re Tobacco II Cases*, 207 P.3d 20, 29 (Cal. 2009); *Frederico v. Home Depot*, 507 F.3d 188, 202 (3d Cir. 2007); *Wilner v. Allstate Ins. Co.*, 893 N.Y.S.2d 208, 214 (App. Div. 2010).

Plaintiffs fail to allege a *single fact* which, if true, would render *any* of the labeling statements false in *any* respect. The Complaint does not explain how the health claims were untrue, and Plaintiffs do not (and cannot) dispute the clinical research supporting these claims. Instead, Plaintiffs contend that the statements “were false, untrue, misleading, unfair, deceptive and/or likely to deceive.” (Compl. ¶ 100; *id.* ¶¶ 31, 63, 64, 99.) These conclusory allegations amount to nothing more than “[t]hreadbare recitals of the elements of a cause of action.” *Iqbal*, 129 S. Ct. at 1949. Even at the pleadings stage, these “‘naked assertion[s]’ devoid of ‘further factual enhancement’” will not suffice. *Id.* (quoting *Twombly*, 550 U.S. at 557).

Nor may Plaintiffs obtain leave to plead specific facts to support their claims, because their lawsuit simply seeks to parrot the FDA staff letter and assert

derivative regulatory violations. (*Supra* pp. 10-16.) But while the FDA is authorized to sanction “false or misleading” labeling, 21 U.S.C. § 343(a)(1), that was not even the basis for any of the violations alleged in the letter. In fact, the FDA clarified that General Mills *was authorized* “to claim that [Cheerios] may lower the risk of coronary heart disease when eaten as part of a diet low in saturated fat and cholesterol,” in light of the “significant scientific agreement among qualified experts to support the relationship between soluble fiber in whole oats and coronary heart disease.” (Ex. F.) Plaintiffs persist in asserting allegations that contradict the FDA’s most recent guidance. (Compl. ¶ 46.) Any remaining dispute involves regulatory compliance, not actual or potential deception.

Controlling precedent distinguishes between ***unauthorized*** claims, on the one hand, and ***deceptive*** health claims, on the other. “Unauthorized” claims cannot give rise to consumer fraud claims merely because the claims are not authorized. The claims must be untrue. For example, the Third Circuit concluded that a plaintiff could not claim that the defendant’s cough syrup label was “misleading to the consuming public,” even though plaintiff submitted evidence that the disputed label may have violated FDA regulations. *Sandoz*, 902 F.2d at 230. *See also In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 06-5774, 2009 WL 2043604, at *13 (D.N.J. July 10, 2009) (“[T]here is a clear and decisive difference between allegations that actually contest the safety or effectiveness of [FDA-regulated products] and claims that merely recite violations of the FDCA”).

Another federal appellate court likewise rejected as “almost frivolous” the

contention that any health claim not authorized by the FDA regulations is “inherently misleading.” *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999). *See also Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 67 (D.D.C. 1998) (scientific conclusions “are not ‘untruthful’ or ‘inherently misleading’ merely because the FDA has not yet had the opportunity to evaluate the claim”), *vacated as moot on other grounds sub nom. Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000). Even crediting the alleged regulatory violations asserted in the FDA staff letter (which General Mills obviously disputes), Plaintiffs have failed to plead facts that would establish actionable deceptive conduct.

Next, Plaintiffs cannot allege a “material” omission on the theory that the failure to recommend eating “fiber-containing fruits and vegetables” implied that Cheerios would reduce cholesterol and other health risks “irrespective of other important dietary considerations.” (Compl. ¶ 46.) For starters, no reasonable consumer could mistake a dried oat cereal for a drug capable of reducing “bad” cholesterol regardless of other dietary choices. Plaintiffs cannot hold General Mills liable for an alleged failure to disclose what “[c]onsumers know as a matter of common sense and knowledge, or ought to be reasonably charged with knowing.” *Gaidon v. Guardian Life Ins. Co.*, 725 N.E.2d 598, 611 (N.Y. 1999).

In any event, General Mills actually provided common-sense context for all consumers: the front and back panels explained that whole grains like Cheerios should be “*part* of a diet low in saturated fat and cholesterol.” (Compl. ¶ 33; *id.* ¶ 30 [“Whole Grain Nation” website recommended Cheerios as “*part* of a healthy

diet”]; *id.* ¶ 26 [General Mills’ website claimed that Cheerios is “clinically proven to lower cholesterol *when eaten as part of a diet low in saturated fat and cholesterol.*”] (emphases added).) In light of the entire package, Plaintiffs cannot plausibly claim that reasonable consumers would mistake Cheerios for an FDA-approved hypercholesterolemia “drug.” *Freeman v. Time, Inc.*, 68 F.3d 285, 289-90 (9th Cir. 1995) (reasonable consumers must read “the promotion as a whole,” including “qualifying language”).

Plaintiffs’ consumer fraud claims also fail the heightened pleading requirement of Rule 9(b), which applies to each element of their California and New Jersey claims grounded in fraud. *See, e.g., Frederico*, 507 F.3d at 200; *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1126-27 (9th Cir. 2009). *See also Masterson Pers., Inc. v. McClatchy Co.*, No. 05-1274, 2005 WL 3132349, at *4-5 (D. Minn. Nov. 22, 2005). To allege fraud with particularity, Plaintiffs “must set forth what is false or misleading about a statement, and why it is false.” *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003). But the Complaint contains only the conclusory averment that the statements *are* false, without any supporting allegations demonstrating *how*, *why*, and *in what respect*. (*See, e.g.,* Compl. ¶¶ 31, 63, 64, 100.) Nor have Plaintiffs included “precise allegations of [the] date, time, or place” they saw the allegedly deceptive claims. In sum, they have not met their burden to “inject[] precision and some measure of substantiation

into their allegations of fraud.” *Naporano Iron & Metal Co. v. Am. Crane Corp.*, 79 F. Supp. 2d 494, 511 (D.N.J. 1999) (citation omitted).¹⁵

2. Plaintiffs Cannot Allege A Legally Cognizable Harm Or Injury

For several different reasons, Plaintiffs also do not allege any “harm” or “injury” to support their consumer fraud claims. Cal. Bus. & Prof. Code § 17204 (requiring “injury in fact and ... lost money or property as a result of” the alleged unfair competition); N.J. Stat. Ann. § 56:8-19 (requiring “ascertainable loss”); *Einhorn v. Mergatroyd Prods.*, 426 F. Supp. 2d 189, 195 (S.D.N.Y. 2006) (New York Gen. Bus. Law § 349(h) requires “actual, direct, non-derivative injury”).¹⁶

¹⁵ The Complaint also fails to state a claim under the “unlawful” and “unfair” prongs of California’s Unfair Competition Law (“UCL”). Alleged regulatory violations cannot support a claim for “unlawful” business practices, because the FDCA expressly vests exclusive enforcement authority in the FDA (21 U.S.C. § 337(a)), and Plaintiffs may not use the UCL to overcome this bar. *See, e.g., Fraker*, 2007 WL 1296571, at *4; *Summit Tech., Inc. v. High-Line Med. Instr. Co.*, 922 F. Supp. 299, 316-17 (C.D. Cal. 1996). The allegations also do not support a claim for “unfair” business practices under any definition of this term: (1) the challenged conduct does not “significantly threaten[] or harm[] competition” or risk an “incipient violation” of antitrust law or policy (*Churchill Vill., L.L.C. v. G.E. Co.*, 169 F. Supp. 2d 1119, 1130 & n.10 (N.D. Cal. 2000); *Mut. Pharm. Co., Inc. v. Watson Pharms., Inc.*, No. 09-5421, 2010 WL 446132, at *7 (D.N.J. Feb. 8, 2010)); (2) in balancing General Mills’ conduct (scientifically-supported health claims) against the alleged “harm to the consumer” (an alleged regulatory violation that caused no harm), the balance tilts strongly in General Mills’ favor (*Lozano v. AT&T Wireless Servs., Inc.*, 504 F.3d 718, 736 (9th Cir. 2007)); and (3) the labeling does not “offend[] an established public policy” (*People v. Casa Blanca Convalescent Homes, Inc.*, 206 Cal. Rptr. 164, 177 (Ct. App. 1984)).

¹⁶ Plaintiffs’ failure to plead a cognizable injury also invalidates each one of their Minnesota state law claims. *See O’Neil v. Simplicity, Inc.*, 553 F. Supp. 2d 1110, 1113 n.4 (D. Minn. 2008), *aff’d*, 574 F.3d 501 (8th Cir. 2009) (actual injury requirement applies to Minnesota’s Deceptive Trade Practices Act, Consumer

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As an initial matter, Plaintiffs’ averment that they “would not have ... paid as much for Cheerios but for the unfair, deceptive and unlawful acts” (Compl. ¶ 105) is the kind of “conclusory” and “formulaic” statement that the Supreme Court has rejected. *Iqbal*, 129 S. Ct. at 1949; *Twombly*, 550 U.S. at 555. Plaintiffs do not even specify whether the Cheerios boxes they allegedly purchased displayed the challenged statements. (Compl. ¶¶ 5-10.) As discussed above, General Mills stopped including the disputed health claims in May 2009. That pleading failure—standing alone—is sufficient to compel dismissal of the case.

Moreover, courts consistently refuse to import Plaintiffs’ “inflated price,” fraud-on-the-market theory from the federal securities law context into consumer law. *See, e.g., Int’l Union of Operating Eng’rs Local No. 68 Welfare Fund v. Merck & Co.*, 929 A.2d 1076, 1088 (N.J. 2007) (“[T]o the extent that plaintiff seeks to prove only that the price charged for [a product] was higher than it should have been as a result of defendant’s fraudulent marketing campaign, and seeks thereby to be relieved of the usual requirements that plaintiff prove an ascertainable loss, the theory must fail.”); *Mirkin v. Wasserman*, 858 P.2d 568, 571 (Cal. 1993) (rejecting plaintiffs’ “plea to incorporate the fraud-on-the-market doctrine into the common law of deceit”). In particular, courts have rejected

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Fraud Act, or False Statement in Advertising Act, and to breach of warranty and unjust enrichment claims). This defect also would require dismissal of Plaintiffs’ “kitchen sink” Count V under 33 other state consumer protection statutes, which require damage or some other pecuniary or ascertainable loss.

analogous attempts to use this “inflated price” theory in actions by drug purchasers (which is what Plaintiffs purport to be). *See In re Schering-Plough*, 2009 WL 2043604, at *20-22 (dismissing New Jersey CFA claims raising inflated price theory in pharmaceuticals context); *Prohios v. Pfizer, Inc.*, 485 F. Supp. 2d 1329, 1336-39 (S.D. Fla. 2007) (dismissing N.Y. Gen. Bus. Law § 349(h) claim asserting inflated price theory in similar context).

Plaintiffs purchased and received exactly what they paid for—cereal with truthful and scientifically-supported health claims. They fail to allege that the cereal was ineffective, “unsatisfactory,” or “worth less” than what they paid for it. *Hall v. Time Inc.*, 70 Cal. Rptr. 3d 466, 471 (Ct. App. 2008). Nor do Plaintiffs contend that they experienced a “loss in value” in the cereal they purchased. *Thiedemann v. Mercedes-Benz USA, LLC*, 872 A.2d 783, 792-93 (N.J. 2005). At most, this lawsuit seeks to manufacture an “injury” from alleged technical violations of FDA regulations recited in a nonbinding FDA staff letter. But alleged regulatory violations do not establish “injury” at all. *Cf. Waste Mgmt. of N. Am., Inc. v. Weinberger*, 862 F.2d 1393, 1398 (9th Cir. 1988) (“Absent injury, a violation of a statute gives rise merely to a generalized grievance but not to standing.”); *Cronson v. Clark*, 810 F.2d 662, 664 (7th Cir. 1987) (“A plaintiff, in order to have standing in a federal court, must show more than a violation of law....”) (citing *Allen v. Wright*, 468 U.S. 737, 754 (1984)).

The Complaint also fails to trace the alleged enticement to buy Cheerios to any concrete injury.¹⁷ This failure to plead causation warrants dismissal: “Even if the deceptive or misleading conduct [plaintiff] refers to has something to do with FDA’s findings described in the warning letters and defendants’ failure to reveal such information to plaintiff, [plaintiff] provides no connection between the defendants’ deceptive conduct and a specific injury that she suffered as a result of that activity.” *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 287 (E.D.N.Y. 2009). *See also Franulovic v. Coca Cola Co.*, No. 07-539, 2007 WL 3166953, at *8 (D.N.J. Oct. 25, 2007).¹⁸

¹⁷ *In re Tobacco II Cases*, 207 P.3d at 39 (requiring plaintiff to show that absent the defendant’s alleged misrepresentation, “the plaintiff ‘in all reasonable probability’ would not have engaged in the injury-producing conduct”) (quoting *Mirkin*, 858 P.2d at 586); *Petinga v. Sears, Roebuck & Co.*, No. 05-5166, 2009 WL 1622807, at *8 (D.N.J. Jun. 9, 2009) (requiring proximate causation to state a claim under the New Jersey CFA); *City of N.Y. v. Smokes-Spirits.Com, Inc.*, 911 N.E.2d 834, 839 (N.Y. 2009) (holding that more than “but for” causation is required to state a claim for relief under Gen. Bus. Law § 349); *Group Health Plan, Inc. v. Philip Morris Inc.*, 621 N.W.2d 2, 13 (Minn. 2001) (plaintiffs must show “causal nexus” by pleading and proving “reliance on [deceptive] statements or conduct alleged to violate [Minnesota consumer fraud] statutes”).

¹⁸ Because Plaintiffs do not allege that they even visited the Whole Grain Nation website (Compl. ¶¶ 26-28, 30), much less purchased Cheerios there, they also cannot allege any causal link to the challenged statements that appeared on that site (the heart disease and cancer claims). *See Dewey v. Volkswagen AG*, 558 F. Supp. 2d 505, 526-27 (D.N.J. 2008) (“With regard to the statements on Volkswagen’s website ... Plaintiffs do not allege ... at what point—if ever—each Plaintiff was exposed to one or more of the statements. Without this information, Plaintiffs have not properly plead a ‘causal nexus’ with the particularity required by Rule 9(b).”); *Gale v. IBM, Corp.*, 781 N.Y.S.2d 45, 47 (App. Div. 2004) (dismissing claim under GBL § 349 on the grounds that plaintiff failed to allege seeing allegedly misleading statement before purchasing product).

C. The Complaint Fails To Plead The Existence Of Any Warranties, Or Injury Caused By Breach Of Warranties

1. Plaintiffs Cannot State A Claim For Breach Of Express Warranty

Next, Plaintiffs attempt to stretch their regulatory claims into an alleged breach of warranty, but the Complaint does not allege the express terms of *any* warranty as required under California, New Jersey, and New York law. *See, e.g., Stearns v. Select Comfort Retail Corp.*, No. 08-2746, 2009 WL 1635931, at *4 (N.D. Cal. June 5, 2009); *Elias v. Ungar's Food Prods., Inc.*, 252 F.R.D. 233, 251 (D.N.J. 2008); *Davis v. N.Y.C. Hous. Auth.*, 668 N.Y.S.2d 391, 392-93 (App. Div. 1998).¹⁹

The closest Plaintiffs come to alleging the requisite “affirmation of fact or promise” exposes a fatal inconsistency in this claim. Although they assert that Cheerios warranted health benefits “irrespective of other important dietary considerations” (Compl. ¶ 110), they also quote qualifying language from the actual labels that refute this assertion: “Three grams of soluble fiber daily from whole grain oat foods, like Cheerios cereal, *in a diet low in saturated fat and cholesterol, may* reduce the risk of heart disease.” (*Id.* ¶ 22; *see also id.* ¶ 23 [“A

¹⁹ Plaintiffs’ failure to allege express affirmations also dooms their claims under all the state express-warranty laws invoked in Count VI. All but one of the states named in that Count follow the Uniform Commercial Code, which requires “affirmation[s] of fact or promise” or an affirmative description of goods to establish an express warranty. UCC § 2-313(2)(a). Plaintiffs’ claim under the laws of Louisiana, which has not adopted the UCC, is barred by Plaintiffs’ failure to allege injury. *Infra* n. 20.

new study proves Cheerios' cereal *plus a reduced calorie diet that is low in fat* can help lower bad cholesterol by about 10% in one month”] (emphases added). Further, this qualified language—“*can*,” “*may help*,” “*may reduce*”—is not a sufficiently definite “affirmation” or “promise” that the product *will* deliver a certain result, so these statements cannot support a warranty claim. *See, e.g., Sidco Prods. Mktg. v. Gulf Oil Corp.*, 858 F.2d 1095, 1099 (5th Cir. 1988) (“[E]xpress warranties must be explicit.”).

At most, Plaintiffs premise their express warranty claim on an alleged *omission* that Cheerios “failed to disclose or adequately disclose ... material facts.” (Compl. ¶¶ 2, 46, 110.) But an express warranty requires an explicit *affirmation* of fact or promise—an alleged omission is insufficient. *See, e.g., Sidco Prods.*, 858 F.2d at 1099 (“Omissions, however, are not affirmative representations of any sort and thus cannot support a warranty claim, because express warranties must be explicit.”); *In re Gen. Motors Corp. Anti-Lock Brake Prods. Liab. Litig.*, 966 F. Supp. 1525, 1531 (E.D. Mo. 1997) (same); *Witherspoon v. Philip Morris, Inc.*, 964 F. Supp. 455, 465 (D.D.C. 1997) (same). Because the Complaint does not allege a viable express warranty claim, Count VI should be dismissed.

2. Plaintiffs Also Cannot Allege A Breach Of Implied Warranty

a. No Breach of the Implied Warranty of Merchantability. Plaintiffs offer no facts to support their absurd (and conclusory) claim that the “ordinary purpose” of Cheerios—a product marketed presently (and for decades before that) *without* the challenged label—is to reduce cholesterol. (Compl. ¶ 122.) Moreover, a food

product is fit for its ordinary use (*i.e.*, it is “merchantable” under UCC § 2-314(2)) if it is fit for human consumption. *See, e.g., Mexicali Rose v. Super. Ct.*, 822 P.2d 1292, 1295-96 (Cal. 1992); *Luna v. Am. Airlines*, No. 04-1803, 2009 WL 4857489, at *5 (S.D.N.Y. Dec. 16, 2009); *Hollinger v. Shoppers Paradise of N.J., Inc.*, 340 A.2d 687, 692-93 (N.J. Super. Ct. 1975). Plaintiffs do not allege (and cannot claim) that Cheerios was unfit for human consumption, so this claim fails.

b. No Breach of the Implied Warranty of Fitness for a Particular Purpose.

Plaintiffs also do not and cannot state a claim for a breach of the implied warranty of “fitness for a particular purpose.” (Compl. ¶ 122.) They impermissibly identify cholesterol reduction (or heart disease and cancer prevention) as both the *ordinary* and *particular* purpose of Cheerios. (*Id.*) But a “‘particular purpose’ differs from the ordinary purpose for which the goods are used in that it envisages a specific use by the buyer which is peculiar to the nature of his business.” N.J. Stat. Ann. § 12A:2-315, cmt. 2; *see also* Cal. Com. Code § 2315, cmt. 2 (same); *Mastrangelo v. Howmedica*, 903 F. Supp. 439, 443 n.1 (E.D.N.Y. 1995) (same). It is impossible for cholesterol reduction to be both the ordinary *and* the particular purpose of Cheerios. *See, e.g., Franulovic*, 2007 WL 3166953, at *4-5 (dismissing implied warranty claim where plaintiff identified weight loss as *both* the particular and ordinary purpose of the soda); *Mathison v. Bumbo*, No. 08-0369, 2008 U.S. Dist. LEXIS 108511, at *29 (C.D. Cal. Aug. 18, 2008) (dismissing implied warranty

claim where plaintiff assigned “securing infants and toddlers” as *both* the particular and ordinary purpose of an allegedly defective baby seat).²⁰

D. Plaintiffs Cannot Claim Unjust Enrichment

Count VIII for unjust enrichment also fails for several independent reasons. First, “there is no cause of action in California for unjust enrichment.” *Melchior v. New Line Prods., Inc.*, 131 Cal. Rptr. 2d 347, 357 (Ct. App. 2003).

Second, Plaintiffs “have not identified a benefit unjustly conferred upon Defendant[] which would warrant Plaintiffs receiving redress.” *Group Health Plan, Inc. v. Philip Morris, Inc.*, 68 F. Supp. 2d 1064, 1071 (D. Minn. 1999). Plaintiffs received the Cheerios cereal for which they paid the various retailers, and they have not alleged that Cheerios was ineffective or defective in any way.²¹

²⁰ Because Plaintiffs purchased Cheerios from grocery stores (Compl. ¶¶ 5-10), they are not in privity with General Mills. The lack of privity defeats their claim under New York law (*Kolle v. Mainship Corp.*, No. 04-711, 2006 WL 1085067, at *5 (E.D.N.Y. Apr. 20, 2006)), and under California law, absent plausible allegations of injury (*see, e.g., Annunziato v. eMachines, Inc.*, 402 F. Supp. 2d 1133, 1141 (C.D. Cal. 2005); *Mexicali Rose*, 822 P.2d at 1295-96). Plaintiffs also have not alleged any injury to support Count VII. *Supra* pp. 30-32; *Heindel v. Pfizer Inc.*, 381 F. Supp. 2d 364, 366 (D.N.J. 2004) (“[S]ince the Plaintiffs suffered no injury,” they could not recover under a theory of implied warranty); *Am. Suzuki Motor Corp. v. Super. Ct.*, 44 Cal. Rptr. 2d 526, 528, 531 (Ct. App. 1995); *Frank v. DaimlerChrysler Corp.*, 292 A.D.2d 118, 121 (N.Y. App. Div. 2002).

²¹ *See also Adamson v. Ortho-McNeil Pharms., Inc.*, 463 F. Supp. 2d 496, 504-05 (D.N.J. 2006) (New Jersey unjust enrichment claim against pharmaceutical manufacturer failed where, notwithstanding allegation of misrepresentations, plaintiff “purchased and paid for” “and received” the disputed drug); *Sokoloff v. Town Sports Int’l*, 6 A.D.3d 185, 186 (N.Y. App. Div. 2004) (New York unjust enrichment claim against health club failed where plaintiff received health club access bargained for); *Rheem Mfg. Co. v. United States*, 371 P.2d 578, 581 (Cal.

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Third, Plaintiffs cannot allege a claim for the quasi-contractual remedy of unjust enrichment because they already allege that the parties' rights are governed by a binding agreement—an express warranty. As the Ninth Circuit has explained, “unjust enrichment is an action in quasi contract, which does not lie when an enforceable binding agreement exists defining the rights of the parties.” *Paracor Fin. v. G.E. Capital Corp.*, 96 F.3d 1151, 1167 (9th Cir. 1996). *See also Cal. Med. Ass’n, Inc. v. Aetna U.S. Healthcare of Cal., Inc.*, 114 Cal. Rptr. 2d 109, 125 (Ct. App. 2001); *Clark-Fitzpatrick, Inc. v. Long Island R.R. Co.*, 516 N.E.2d 190, 193 (N.Y. 1987) (same). Nor may Plaintiffs amend their Complaint to allege unjust enrichment in the alternative. *See, e.g., Gerlinger v. Amazon.com*, 311 F. Supp. 2d 838, 856 (N.D. Cal. 2004) (“Even though Rule 8(e)(2) of the Federal Rules of Civil Procedure allows a party to state multiple, even inconsistent claims, it does not alter a substantive right between the parties and accordingly does not allow a plaintiff invoking state law to an unjust enrichment claim while also alleging an express contract.”); *Aprile Seafreight S.P.A. v. Global Freight, Inc.*, No. 05-4850, 2005 U.S. Dist. LEXIS 32797, at *7 (N.D. Ill. Dec. 12, 2005).

Finally, Plaintiffs' conclusory statement that they “conferred benefits to” General Mills is insufficient to warrant restitution. (Compl. ¶ 135.) They do not allege that they paid any money *directly* to General Mills. Nor do Plaintiffs allege

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1962) (proof of payment of fair market value in exchange for property “tends to show that there was no unjust enrichment”).

any facts to establish that General Mills' retention of the price paid by food wholesalers or retailers was "unjust" or "inequitable." *See, e.g., Marina Tenants Ass'n v. Deauville Marina Dev. Corp.*, 226 Cal. Rptr. 321, 328 (Ct. App. 1986) ("A mere allegation that [defendants] have wrongfully acquired excessive rentals and become unjustly enriched does not entitle the [plaintiffs] to relief").

E. There Is No Basis For Injunctive Relief Because The Challenged Statements No Longer Appear On The Cheerios Packaging

Finally, at a minimum, the Court should strike Plaintiffs' request for injunctive relief. General Mills revised the labeling at issue nearly a year ago, and the current Cheerios packaging does not contain health claims identified in the Complaint. (Hingher Decl. ¶¶ 4-7; *supra* p. 8 & n.4.) Given this voluntary labeling change, there is no ongoing practice to "enjoin." *See, e.g., United States v. Or. State Med. Soc.*, 343 U.S. 326, 333 (1952) ("The sole function of an action for injunction is to forestall future violations."); *Sun Microsystems, Inc. v. Microsoft Corp.*, 188 F.3d 1115, 1123 (9th Cir. 1999) (vacating injunction because defendant had discontinued the challenged practices).

**VII.
CONCLUSION**

Plaintiffs cannot base this putative nationwide class action lawsuit on a preliminary and nonbinding FDA staff letter. The same law that empowers the FDA to send that letter expressly preempts these derivative regulatory claims, bars Plaintiffs' private enforcement attempt, and vests the FDA with primary jurisdiction over the scientific and regulatory issues at the heart of this case. In

addition, Plaintiffs have alleged no basis for applying Minnesota law (or the laws of the other states where they do not reside) to this putative nationwide class action, and their individual state law theories of recovery are defective on multiple additional grounds.

For these reasons, General Mills respectfully requests that the Court dismiss this action with prejudice.

DATED: April 28, 2010

GIBSON, DUNN & CRUTCHER LLP
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CERTIFICATE OF SERVICE

I hereby certify that on April 28, 2010, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will automatically send a notice of electronic filing to all persons registered for ECF as of that date. I also hereby certify that the foregoing document was emailed to Plaintiffs' Liaison Counsel at the below-listed address:

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